



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0659]

Shashikant Shah: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debaring Shashikant Shah for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Shah was convicted of one count of conspiracy to commit an offense against the United States for conduct relating to the development and approval, including the process for development and approval, of a drug product and to the regulation of drug products under the FD&C Act. In addition, the type of conduct underlying the conviction undermined the process for the regulation of drugs. Mr. Shah was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Shah failed to request a hearing, which constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 4144, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds that the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or relating to the regulation of any drug product under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On December 17, 2010, judgment was entered against Mr. Shah in the U.S. District Court for the District of New Jersey based upon a plea of guilty to one count of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for the conviction is as follows: Mr. Shah was employed at Able Laboratories, Inc. (Able) as vice president of quality assurance/quality control and regulatory affairs from in or around mid-1999 through in or around December 27, 2004. Able developed, manufactured, and sold several generic drug products, including products for cardiac and psychiatric conditions and prescription pain relievers.

As Able's vice president of quality control and regulatory affairs, Mr. Shah was responsible for supervising as many as 100 employees, including numerous managers and supervisors, and several laboratory chemists. Mr. Shah's other responsibilities included

supervising the quality control and testing processes of the drug products manufactured and sold by Able, ensuring compliance with current Good Manufacturing Practices, as required by the FD&C Act and FDA regulations.

From in or around 1999 through on or about May 19, 2005, Mr. Shah conspired to cause the introduction and delivery for introduction into interstate commerce of a drug that was adulterated and misbranded, with an intent to defraud and mislead, contrary to 18 U.S.C. 371 and 21 U.S.C. 331(a) and 333(a)(2).

Mr. Shah and his co-conspirators impaired, impeded, defeated, and obstructed FDA's lawful government function to approve the manufacture and distribution of generic drug products by violating Good Manufacturing Practices; violating standards of procedure by failing to properly investigate, log, and archive questionable, aberrant, and unacceptable laboratory results so that Able could conceal improprieties and continue to distribute and sell its drug products; manipulating and falsifying testing data and information to conceal from FDA failing laboratory results relating to Able's generic drug products; creating and maintaining false, fraudulent, and inaccurate test results to make it appear that drug products had the requisite identity, strength, quality, and purity characteristics so the drug products could be distributed and sold to increase Able's sales and profit; and creating and maintaining false, fraudulent, and inaccurate data and records to obtain FDA approval to market new product lines.

In furtherance of the conspiracy, in or around 2002, Mr. Shah supervised the falsification of testing data for Able's butalbital, acetaminophen, and caffeine products. In or around 2003, Mr. Shah supervised the falsification of testing data for Able's methylphenidate product. Mr. Shah additionally directed and supervised the creation of false and fraudulent entries in chemist laboratory notebooks, and in the corresponding process validation binders, relating to Able's

abbreviated new drug application for lithium carbonate extended release tablets, for which Able received FDA approval on or about April 21, 2003.

As a result of his conviction, on December 20, 2011, FDA sent Mr. Shah a notice by certified mail proposing to debar him for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(II) of the FD&C Act that Mr. Shah was convicted of a conspiracy under Federal law for conduct relating to the development and approval, including the process for development and approval of a drug product, and to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermined the process for the regulation of drugs. The proposal also offered Mr. Shah an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Shah failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under Section 306(b)(2)(B)(i)(II) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Shashikant Shah has been convicted of a conspiracy under Federal law for conduct relating to the development and approval, including the process for development and approval of a drug product, and to the regulation of drug products under the FD&C Act, and

that the type of conduct that served as a basis for the conviction undermined the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Shah is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD& C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Shah, in any capacity during Mr. Shah's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Shah provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Shah during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Shah for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 355a(d)(1)) should be identified with Docket No. FDA-2011-N-0659 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2012.

Armando Zamora,

Acting Director,

Office of Enforcement,

Office of Regulatory Affairs.

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